510(k) Summary

APR 0 2 2014

Submitter information

Company name	Materialise N.V.
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Submission date

The date of the Traditional 510(k) submission is , January 29th 2014.

Submission information

Trade Name	Signature Planner Signature guides
Common Name	Patient specific instrumentation for knee arthroplasty
Classification Name	- Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis -Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis.
Primary product code	MBH (21 CFR § 888.3565)
Subsequent product codes	OOG, JWH, OIY and MBV

Predicate devices

Predicate Device	
Trade or proprietary or model name	Signature Personalized Patient Care System
510(k) number	K102795
Decision date	2 February 2011
Product code	JWH/OIY, MBH, OOG
Manufacturer	Materialise N.V.

Predicate Device	
Trade or proprietary or model name	Signature Personalized Patient Care System
510(k) number	K110415
Decision date	16 May 2011
Product code	HRY, JWH, OIY, MBH, OOG
Manufacturer	Materialise N.V.

Predicate Device	
Trade or proprietary or model name	Vanguard XP Knee System
510(k) number	K122160
Decision date	20 March 2013
Product code	MBH, JWH, MBV, OIY
Manufacturer	Biomet Manufacturing, Corp.

Device Information

Description of the device

The **Signature Personalized Patient Care System** consists of a software component, **Signature Planner** and a hardware component, **Signature guides** and is designed to assist the surgeon in the placement of Biomet total knee replacement components.

Functioning of the device

The **Signature guides** are patient specific devices that are based on a pre-operative plan which is generated using the **Signature Planner** software. The **Signature guides** are produced based on the pre-operative plan and are manufactured to fit a specific patient. The Signature Planner software functions essentially the same as in K102795 and K110415, but is adapted to allow the use of Biomet Vanguard™ XP Knee system (K122160) for total knee arthroplasty procedures.

The subject guides are intended for the total knee arthroplasty procedures and represent a combination of design and functionality of those in K102795 and K110415. The Vanguard XP-CR tibial tray will utilize the guides cleared in K102795/K110415 as they have the same profile/bone interface as the predicates. The Vanguard XP-XP tibia guide have similar vertical cut slots as partial tibia guide in K110415. The vertical cut-through slots allow for preliminary cuts of the bone, before final cuts are made and the implant is placed.

Intended use

Pin Placement Guides

Signature Personalized Patient Care System is intended to be used as a surgical instrument to assist in the positioning of total knee replacement components intra-operatively and in guiding the marking of bone before cutting provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans.

The **Signature Personalized Patient Care System** can be used with the following Biomet® Knee Systems and their respective components: Vanguard™ Complete Knee System, Vanguard™ SSK 360, Vanguard™ SSK Revision Knee System, Regenerex™ Primary Tibial System, Offset & Microplasty™ Tibial Systems, Maxim™ Complete Knee System, Ascent™ Total Knee System, AGC™ Complete Knee system and Vanguard™ XP Knee system.

Cut-Through Guides

Signature Personalized Patient Care System is intended to be used as a surgical instrument to assist in the positioning of total and partial knee replacement components intra-operatively and in guiding the marking of bone before cutting and to guide cutting, provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans.

The **Signature Personalized Patient Care System** can be used with the following Biomet® Knee Systems and their respective components: Vanguard™ Complete Knee System, Vanguard M™ Unicompartmental Knee System, Vanguard™ SSK 360, Vanguard™ SSK Revision Knee System, Regenerex™ Primary Tibial System, Offset & Microplasty™ Tibial Systems, Maxim™ Complete Knee System, Ascent™ Total Knee System, AGC™ Complete Knee system and Vanguard™ XP Knee system.

The **Signature Personalized Patient Care System** is compatible for use with the Oxford® Partial Knee System as approved in P010014/S31.

The **Signature guides** are intended for single use only.

Summary of technological characteristics

Device comparison showed that the proposed device is substantially equivalent to the Signature Personalized Patient Care System in K102795 and the Signature Personalized Patient Care System in K110415 in terms of intended use, design, functionality, materials, fundamental technology and performance characteristics.

Performance data

Non-clinical tests

The Signature Planner software has been validated for its intended use to determine substantial equivalence to the predicate devices.

Accuracy performance testing by means of two cadaveric trials, and guide deformation verification after sterilization was performed to determine substantial equivalence. Testing verified that the accuracy and performance of the system is adequate to perform as intended.
A debris rationale is provided to illustrate substantial equivalence with the predicate devices.

Clinical data

Not applicable.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 2, 2014

Materialise N.V.
Mr. Oliver Clemens
Quality and Regulatory Officer
Technologielaan 15
Leuven, Belgium 3001

Re: K140257
Trade/Device Name: Signature Personalized Patient Care System (Signature Guides, Signature Planner 8.0)
Regulation Number: 21 CFR 888.3565
Regulation Name: Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: MBH, OOG, JWH, OIY, MBV
Dated: January 29, 2014
Received: February 3, 2014

Dear Mr. Clemens:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K140257

Device Name: Signature Personalized Patient Care System (**Signature Guides, Signature Planner 8.0**)

Indications for Use:

Pin Placement Guides

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The **Signature Personalized Patient Care System** is compatible for use with the Oxford® Partial Knee System as approved in P010014/S31.

The **Signature guides** are intended for single use only.

Prescription Use _ X ____ AND/OR Over-The-Counter Use __ _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices